REMARKS

This Amendment is in response to the Office Action dated April 30, 2009, setting a three-month period of response ending July 30, 2009. Also enclosed herewith is a two-month Petition for Extension of Time to extend the deadline up to and including September 30, 2009. Entry and consideration of the following amendments and remarks is respectfully requested.

Claims 16, 19-30, 37-40 and 43-50 are currently pending in this application, of which claims 16, 27, 37, 44 and 48 are independent. Claims 41 and 42 have been cancelled. Claim 44 is newly added and claims a method of providing an individual syringe and associating a unique tracking code with that individual syringe. Claims 45-47 claim that the unique tracking code is written on a bar code, located on the single source, and further that additional markings may be present on the syringe such as hand-written or type-written materials, including patient information, drug information and/or other bar codes. Claim 48 is also newly added and claims a method of providing an individual syringe and associating a unique tracking code, written on a bar code, with that individual syringe. Claims 49 and 50 claim that the unique tracking code is written on a bar code, located on the single source, and further that additional markings may be present on the syringe such as hand-written or type-written materials, including patient information, drug information and/or other bar codes. Claims 16 and 27 have been amended to further define that the tracking code, on the medical device, conveys no other information than the identity of the tracking code itself, and that the tracking code is related to the medical device, which contains the drug. Claim 37 has been amended to further define the "single source" to be "an individual syringe."

As an initial matter, Applicants would like to thank Examiner for participating in an Interview on September 16,

2009. During the Interview, Examiner and Applicant discussed the pending Office Action, and specifically the rejections and the cited prior art on which the rejections are based. Applicant presented various claim amendments and arguments, which Examiner considered. No decision was reached as to the claim amendments or arguments.

Applicants take this opportunity to clarify statements made in the response to the previous office action, dated February 4, 2009. Namely, Applicants stated that "the tracking code, which is the only information on the single source itself, retrieves the information relating to the tracking code from the storage device since the information is not found on the single source itself." Page 10, line 8. The "single source" of this invention includes a unique tracking code, typically found as a barcode or the like, which is the only information on the barcode (or the like). See Paragraphs [0009], [0027]. Thus, the unique tracking code, on the bar code, is machine readable information. The single source may, however, have other writing, typing, symbols, machine readable information, etc. on the single source, as may be desirable, for example, by various medical associations, rules and guidelines. See Paragraph [0028]. While the unique tracking code is the only information found on the barcode (and when scanned, the unique tracking code only has information identifying the unique code - see amendments to claims 16 and 27, claim 43), other information, writing, machine readable information, etc. may be present elsewhere on the single source. Applicants, by including the above statement in the previous Response, were intending to state that the unique tracking code is isolated on a bar code and is the only information on the barcode, such that the unique tracking code only includes information as to the identity of the unique tracking code. However, Applicants did not clarify

that other information (as writing, other bar codes, etc.) may be located on the single source as well.

Claim Rejections under 35 U.S.C. §103(a)

In the Office Action, Examiner rejected claims 16, 19-30 and 38-40 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,651,775 (Walker et al.) in view of U.S. Patent No. 6,170,746 (Brook et al.). Walker et al. and Brook et al. have formed the basis of rejections in previous office actions, thus a summary will not be provided here.

It is respectfully submitted that the combination of Walker et al. and Brook et al. do not disclose each and every element of the claimed invention. First, Applicants assert that the combination of Walker et al. and Brook et al. is improper. Second, even if the combination were proper, it does not disclose the claimed invention.

Applicants submit that the combination of Walker et al. and Brook et al. is improper for at least the reason that they seek to rectify two different problems and thus present two different solutions. Essentially, Walker et al. seek to track administration of a drug to a patient, while Brook et al. seek to keep track of overall inventory of vials of a drug throughout a facility, such as a hospital or similar facility. For example, in use, a hospital, or similar facility, would include the Brook et al. invention to track the general inventory of drugs within a hospital supply room. Walker et al. on the other hand would be used to track the administration amount of a drug to a specific patient. Thus, these two systems cannot be combined as suggested by the Examiner since they are directed at very different applications and uses.

Modifying Walker et al. with Brook et al. as suggested would not modify Walker et al. in any meaningful way. Instead, Walker et al. would maintain its original intended use (tracking drug administration), and Brook et al. would only add the

additional process of inventory control to Walker et al. This is not a valid combination of references as they do not seek to solve the same problems and further the solutions presented in each reference are fundamentally different. MPEP §2143.01.

Moreover, Walker et al. and Brook et al. cannot be combined for the reason that they do not track similar containers. Walker et al. track the administration of a drug to a patient from a syringe or other administration device, while Brook et al. track a drug in bulk, i.e., in a vial or similar container, not its administration to a patient. Brook et al. do not disclose tracking an individual syringe or the like. This is a further reason why the two references cannot be combined. Instead, Walker et al. are directed to tracking the administration of drugs to a patient from a syringe (or the like). Brook et al., on the other hand, are not concerned with tracking individual drugs going to specific patients. Instead, Brook et al. are directed to tracking overall quantity of vials of a type of drug, and tracking the total supply of a drug within a facility.

For at least these reasons, Walker et al. and Brook et al. cannot be combined. They are directed to very different processes and systems and are relevant to entirely different needs and requirements of a facility. Applicant thus respectfully requests this combination be withdrawn.

Even if the combination were deemed proper, the combination of Walker et al. and Brook et al. does not disclose each and every element of the invention as claimed.

As discussed in previous office actions, Walker et al. disclose a system which includes a barcode on a syringe, but the barcode includes various administration information such as type of drug, patient, volume, etc. inside the barcode located on the syringe. Walker et al. do not include a central network and do not include a tracking code. Instead, the administration

information is located in the barcode itself. Brook et al., on the other hand, do include a central network. However, the barcode on each vial of drug is generic as to a type of drug, and thus every vial that has one type of drug has the same barcode (in fact, Brook et al. merely use the National Drug Code (NDC) for classifying each drug in the inventory, which is a generic code for the drug used throughout every pharmacy, hospital etc. Col. 5, lines 51-54.). Brook et al. do not disclose a unique tracking code, neither does Walker et al.

Based on the Interview with the Examiner, Applicant has amended claims 16 and 27 to include more detail as to the unique tracking code. Specifically, Applicant seeks to claim that the unique tracking code is unique as to a single source, and the single source includes an "individual medical device." The specification as originally filed defines "medical device" in Paragraph [0007]. Thus, claims 16 and 27 now specifically claim that the unique tracking code is unique as to the syringe, and the drug is contained within the individual medical device.

Applicants have also referred to this definition (Paragraph [0007]) in claims 37, 44 and 48, such that the single source includes an individual syringe. Thus, as claimed, the "unique tracking code" is unique as to a "single source," and the single source is an "individual syringe." Thus, the unique tracking code of this Application is unique as to a syringe. The contents of the syringe, the patient it is going to, the volume of drug, etc. are meaningless as to the uniqueness of the unique tracking code. The unique tracking code is unique because it is stored in a remote storage device and assigned to an individual medical device, not because the individual medical device has a specific drug or the individual medical device is assigned to a specific patient.

The combination of Walker et al. and Brook et al. does not disclose this element of the claimed invention. Neither

reference discloses a unique tracking code, unique to an individual medical device. Furthermore, neither reference discloses a single source, having a unique tracking code, wherein the unique tracking code conveys no other information than the identity of the unique tracking code itself. Walker et al. and Brook et al. both include additional information, written into the barcode, including the drug reference, patient, volume, etc. Walker et al., col. 6, lines 25-37; Brook et al., col. 5, lines 51-54. Instead, Brook et al. are concerned with tracking a drug, and specifically, with tracking an inventory of a drug throughout a facility. Walker et al. are also concerned with tracking administration of a drug in a specific syringe. The claimed invention, however, is aimed at tracking a specific medical device, regardless of what is inside the medical device, using a unique tracking code. The claimed invention tracks a specific, individual medical device from preparation, to use, to disposal, and does so using a unique tracking code embedded in the medical device.

Neither of the references, nor their combination, discloses this aspect of the claimed invention. As such, Applicant requests this rejection be withdrawn.

Claims 19-26, 28-30 and 38-40 all depend from claims 16 and 27 (except claim 40, which appears to have been mistakenly included in this rejection as it is dependent on claim 37, not rejected). By virtue of this dependence, each of these claims must also be nonobvious.

Newly added claims 44 and 48 are likewise not unpatentable in view of Walker et al. and Brook et al. As discussed above, both claim a single source, a syringe, being associated with a unique tracking code. As claimed, the tracking code is not related to the drug itself, but is instead related only to the syringe. Neither of the references discloses this element of the claims. Walker et al. do not

disclose a tracking code, and Brook et al. disclose a code assigned to a drug, whereby the code is generic to every container holding the drug. Thus, in Brook et al., multiple containers have the same code. Therefore, claims 44 and 48 are not unpatentable as well.

Claim 37 was rejected under 35 U.S.C. §103(a) as being unpatentable over Brook et al. in view of Walker et al.

Similar to above, the combination of Brook et al. and Walker et al. is improper and should be withdrawn. However, in the event the combination is proper, it is respectfully submitted that, for the reasons stated above, the combination does not disclose each and every element of the claimed invention.

Claim 37 has been amended to define the "single source" as an "individual syringe," and a unique tracking code is associated with the individual syringe. None of Walker et al., Brook et al., or their combination disclose this element of claim 37 (which is also found in claims 44 and 48). Similar to the discussion regarding claims 44 and 48 above, neither reference discloses a unique tracking code unique as to a single, individual syringe. Moreover, Brook et al. do not even disclose the use of the system with a syringe. For at least these reasons, claim 37 is not unpatentable in view of this combination of references.

Similarly, claims 44 and 48 are also not unpatentable for similar reasons. Also, claims 45-47, 49 and 50 are also not unpatentable, by virtue of their various dependencies on claims 44 and 48. Moreover, claims 45-47, 49 and 50 seek to isolate the unique tracking code from other forms of information which may be present on the single source. For example, the single source may include other written, typed or machine readable information which may include, for example, patient information, drug information, administration information, or the like. This

type of information is distinct from the unique tracking code. The unique tracking code does not include this type of "other" information, and is instead merely a tracking code which contains information only as to the identity of the unique tracking code. The barcode containing the unique tracking code only contains the unique tracking code. The other information which may be included on the single source is not on this barcode, but is instead located on another area of the single source (which may include a second bar code, or hand/typed written information).

As to Examiner's Response to Arguments (Letter "C", Page 13), Applicant respectfully submits that the citation produced by Examiner only further proves Applicant's point. The Brook et al. system can save data on the central network, but only as to a drug, not as to a specific individual container (despite the fact the container is also not a syringe). Brook et al. cannot distinguish between specific containers of a drug. Instead, Brook et al. can only distinguish one drug from another, but within a single drug, every container is viewed as the same.

Thus, Applicant respectfully requests this rejection be withdrawn.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: September 30, 2009

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